

24 August 1999

Dockets Management Branch (HFA-305)  
Food & Drug Administration  
5630 Fishers Lane, Room 1061  
Rockville MD 20852

0894 '99 SEP -3 A11:55

FDA guidelines issued April 6, 1999 instituted a de facto ban on nonhuman primate xenografts because they would expose patients and the public to significant infectious disease risk. However, these guidelines failed to address the dangers when using other species, more specifically the swine.

Transgenic pigs are the source animals of choice for xenotransplants despite the existence of over 25 diseases in pigs that can affect humans. Witness swine influenza, the Porcine Endogenous Retroviruses, paramyxovirus and the new "Nipah" virus in Malaysia that infected over 250 humans, killed 100 people and led to the slaughter of some one million pigs.

There are safer, more cost-effective and humane alternatives to xenotransplantation that are not being explored by regulatory authorities. Preventative medicine programs to reduce the need for transplants of organs and increasing the pool of human organs are two alternatives which should be explored and developed.

We urge the Department of Health & Human Services ban xenotransplantation from all nonhuman species.

We trust you share our concern about the complexities and dangers involved in xenotransplants.

NAME	ADDRESS
MADELINE BOLCOL	15 WAKEFIELD CT. BELMONT CA 94002
Deniz Parie	P.O. Box 5656 Redwood City 94063
S. BANCROFT	3027 BARNEY, MENLO PARK CA 94025
Jale Pace	22276 De Anza Circle Cupertino CA 95014
KUWA & KEN RACE	906 Liberty Ct. Cupertino CA 95014
Gina Doraghar	P.O. Box 134 San Carlos 94070
Thomas R. Redlich	

99D-0557

C320



M. Bolbol  
15 Wakefield Court  
BBelmont CA 94002



Dockets Management Branch (HFA-305)  
Food & Drug Administration (Dept/HHS)  
5630 Fishers Lane, Room 1061  
Rockville MD 20852

20837-0001

